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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/647,766  | 08/25/2003  | Patricia K. Somers   | ATH 109 CON6        | 2747             |
| 20786   | 7590        | 09/26/2005           | EXAMINER            |                  |
| KING & SPALDING LLP<br>191 PEACHTREE STREET, N.E.<br>45TH FLOOR<br>ATLANTA, GA 30303-1763 |             |                      | OH, TAYLOR V        |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1625                |                  |

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/647,766

Applicant(s)

SOMERS, PATRICIA K.

Examiner

Taylor Victor Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

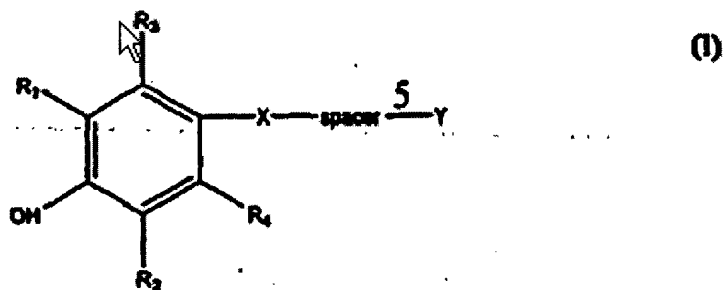
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550

## Restriction/Election

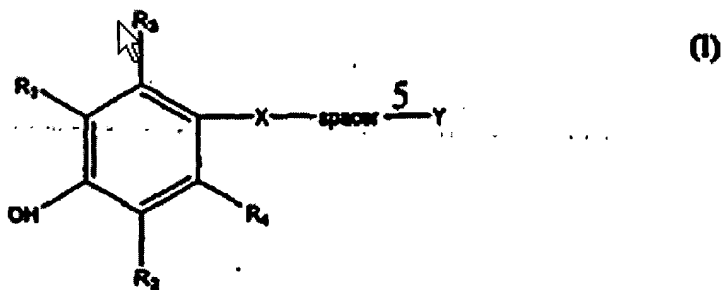
Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to compounds and their pharmaceutical compositions as shown in formula (I):



, classified in classes /subclasses 562/ 426, 562/427, and other non-hetero classes /subclasses .

- II. Claims 1-4, drawn to compounds and their pharmaceutical compositions as shown in formula (I):

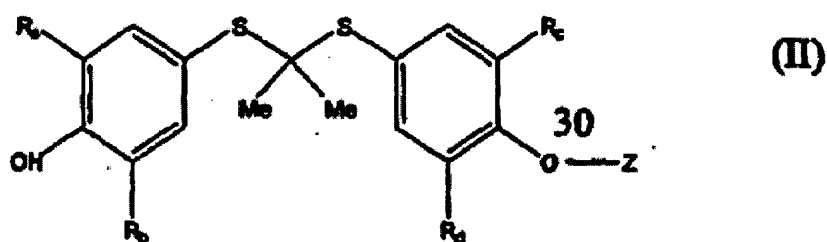


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, classified in classes /subclasses 540/604, 546/192, 548/542, 540/604, 546/192, 548/542, 549/429 and other hetero classes /subclasses .

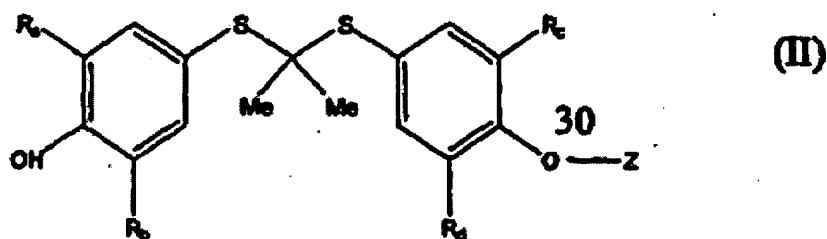
III. Claims 5-9, drawn to a method of treating a disease mediated by the expression of VCAM-1 using an effective amount of the compounds of formula (I), classified in classes /subclasses 514/217.11 and 514/408.

IV. Claims 10-13, , drawn to drawn to compounds and their pharmaceutical compositions as shown in formula (I):



, classified in class 560, subclasses 9 and 16 and other non-hetero classes/subclasses.

V. Claims 10-13, , drawn to drawn to compounds and their pharmaceutical compositions as shown in formula (I):



, classified in classes /subclasses : 546/93; 548/300; 544/106; 548/146; 546/184;  
544/358; 549/182 and other hetero classes /subclasses.

VI. Claims 14-22, drawn to a method of treating a disease mediated by the expression of VCAM-1 using an effective amount of the compounds of formula (II), classified in classes /subclasses 514/562, and 514/602.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case, the invention of Group I is directed to compounds and their pharmaceutical compositions as shown in formula (I) with non-hetero groups in the side branches of the core structure, whereas the invention of Group II is directed to compounds and their pharmaceutical compositions as shown in formula (I) with hetero groups in the side branches of the core structure. They have different modes of

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operation , different functions or different effects because each of them has a completely different chemical structure with respect to the core structure. For example, the formula (I) containing a hetero group has been known to have a different reactivity or a different effect in comparison with the one with the non-hetero groups. Therefore, Group I and Group II are unrelated to each other.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case , the invention Group I can be used for the treatment of cardiovascular and inflammatory diseases mediated by VCAM-1; however, the invention III can be practiced without using the invention Group I ; Medford et al (US 5,750,351) has shown that the cardiovascular and inflammatory diseases mediated by VCAM-1 can be treated by using different compounds ,such as nicotinic acid and aspirin. Therefore, Group I and Group II are unrelated to each other with respect to the relationship between product and process of use.

Inventions Group I and Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

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modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case , the invention of Group I is directed to compounds and their pharmaceutical compositions as shown in formula (I) with non-hetero groups in the side branches of the core structure, whereas the invention of Group IV is directed to compounds and their pharmaceutical compositions as shown in formula (II) with non-hetero groups in the side branches of the core structure. They have different modes of operation , different functions or different effects because each of them has a completely different chemical structure with respect to the core structure. Therefore, Group I and Group IV are unrelated to each other.

Inventions Group I and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case , the invention of Group I is directed to compounds and their pharmaceutical compositions as shown in formula (I) with non-hetero groups in the side branches of the core structure, whereas the invention of Group V is directed to compounds and their pharmaceutical compositions as shown in formula (II) with hetero groups in the side branches of the core structure. They have different modes of operation , different functions or different effects because each of them has a

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completely different chemical structure with respect to the core structure. Therefore, Group I and Group V are unrelated to each other.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the invention Group II is directed to compounds and their pharmaceutical compositions as shown in formula (I) with hetero groups in the side branches of the core structure, whereas the invention III can be practiced without using the invention Group II; Medford et al (US 5,750,351) has shown that the cardiovascular and inflammatory diseases mediated by VCAM-1 can be treated by using different compounds, such as nicotinic acid and aspirin. Therefore, Group II and Group III are unrelated to each other with respect to the relationship between product and process of use.

Inventions Group II and Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case, the invention of Group II is directed to compounds and their pharmaceutical compositions as shown in formula (I) with hetero groups in the side



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branches of the core structure, whereas the invention of Group IV is directed to compounds and their pharmaceutical compositions as shown in formula (II) with non-hetero groups in the side branches of the core structure. They have different modes of operation, different functions or different effects because each of them has a completely different chemical structure with respect to the core structure. Therefore, Group II and Group IV are unrelated to each other.

Inventions Group II and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case, the invention of Group II is directed to compounds and their pharmaceutical compositions as shown in formula (I) with hetero groups in the side branches of the core structure, whereas the invention of Group V is directed to compounds and their pharmaceutical compositions as shown in formula (II) with non-hetero groups in the side branches of the core structure. They have different modes of operation, different functions or different effects because each of them has a completely different chemical structure with respect to the core structure. Therefore, Group II and Group IV are unrelated to each other.

Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

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process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case , the invention Group II is directed to compounds and their pharmaceutical compositions as shown in formula (I) with hetero groups in the side branches of the core structure, whereas the invention VI can be practiced without using the invention Group II ; Medford et al (US 5,750,351) has shown that the cardiovascular and inflammatory diseases mediated by VCAM-1 can be treated by using different compounds ,such as nicotinic acid and aspirin. Therefore, Group II and Group VI are unrelated to each other with respect to the relationship between product and process of use.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, III, IV, V, or VI; the search required for Group II is not required for Group III, IV, V, or VI; restriction for examination purposes as indicated is proper.

Furthermore, these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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A telephone call was made to Sherry M. Knowles on 9/21/05 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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9/21/05